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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/639,690	08/16/00	BENSON	A 101997-5

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EXAMINER	
GANSHEROFF, L	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/639,690	Applicant(s) BENSON, ANDREW K.	
	Examiner Lisa J. Gansheroff	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Application/Control Number: 09/639,690
Art Unit: 1636

DETAILED ACTION

Pending claims: 1-22

Claims drawn to the elected invention: 1-9 and 14-21.

Claims withdrawn from consideration: 10-13 and 22.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 17, drawn to a method of food product testing, classified in class 435, subclass 6.

II. Claims 10-13, drawn to a probe array, classified in class 536, subclass 24.3.

III. Claims 14-16 and 18-21, drawn to a testing method, classified in class 435, subclass 6.

IV. Claim 22, drawn to an apparatus for detecting gene sequences, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

Invention II and inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the probe array could be used to evaluate the levels of expression of different genes when organisms are grown in different conditions.

Inventions I and III are related to invention IV as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be

practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the processes can be practiced by hand.

Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination is an apparatus for automating DNA preparation for detection by the probe array (the subcombination). The subcombination has separate utility such as a way to measure gene expression levels wherein the steps of DNA preparation and primer and probe addition are performed by hand.

The methods of Groups I and III are distinct from each other, and thus one does not render the other obvious. The method of Group I is a testing process for food products, and the method of Group III is a testing process for other types of samples. Thus, the samples to be analyzed in the method and the target DNA sequences on the probe array would be distinct; the databases to be mined would be different; and the results would be different based on the different species likely to be found in different types of samples. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Michael Falkoff on 15 November, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-9 and 17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-16 and 18-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Upon consideration of the prior art, the Examiner has chosen to rejoin the two method groups (I and III), since the prior art discloses methods using probe arrays to test food product samples as well as other types of samples (for example: clinical samples, water samples, environmental samples), and thus one would be obvious over the other. Thus, claims 1-9 and 14-21 were examined.

Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The instant abstract appears to be too long.

Claim Objections

Claim14 is objected to because of the following informalities: there appears to be a comma missing at the end of the third line of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds are of "preparing a food sample".

In claim 7, it is not clear how "including a data mining program..." is related to the preceding part of the claim.

In claim 8, the phrase "recovering plural different microorganisms" is unclear. Do Applicants intend a plurality of different microorganisms?

In claim 9, there appears to be a Markush group, but it is not written in proper Markush language. It is also not clear what is intended by the phrase "food parameters", and it is not clear what the metes and bounds are of the phrase "process history parameters".

In claim 18, it is not clear what is meant by "species sequences coding for pathogenicity or virulence". Do Applicants intend that the sequences encode virulence factors or factors involved in pathogenesis?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 14, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Heyneker (U.S. Patent 6,057,100).

Heyneker teaches oligonucleotide arrays (probe arrays) and teaches that they can be used in method to detect microorganisms in food and other samples. Heyneker teaches that the oligonucleotide arrays are designed to detect target sequences from a variety of bacteria and viruses (column 8, lines 57-61) and that a preferred embodiment is that the nucleic acids of the invention find use as probes for toxic bacteria in the screening of water and food samples (column 9, lines 5-7). Heyneker teaches that "samples may be treated to lyse the bacteria to release its nucleic acid, and then oligonucleotides designed to recognize bacterial strains, including, but not limited to, such pathogenic strains as, Salmonella, Campylobacter, Vibrio cholerae, enterotoxic strains of E. coli, and Legionnaire's disease bacteria" (column 9, lines 7-15). Heyneker teaches that samples are treated as is known in the art, including any sample preparation such as purification or amplification, followed by labeling of the target sequences..." (column 9, lines 19-35). Heyneker also teaches that the oligonucleotide array comprises a plurality of different oligonucleotide pools (see, for example, claim 1 of the reference).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyneker et al., as applied to claims 1-4, 14, and 17-19 above, and further in view of Anderson

et al. (U.S. Patent 5, 922, 591), Bruckner-Lea et al. (1996), Bergeron et al. (U.S. Patent 6,001,564), Nakayama et al. (U.S. Patent 5795717), and Tauxe (1997).

Heyneker et al. teaches methods using oligonucleotide probe arrays to detect bacteria in food samples. Heyneker et al. does not teach automated fluidics.

Anderson et al. teaches a combination of oligonucleotide probe arrays and automated fluidics for use in nucleic acid based diagnostic applications and other applications (see Abstract and claims 52 and 53). Anderson et al. teach that following amplification and/or labeling, the nucleic acid sample is incubated with the oligonucleotide array in the hybridization chamber, and hybridization between the sample nucleic acid and the probes on the array are detected (column 15, lines 4-11). Anderson et al. teach that data gathering methods are known in the art and readily automated for detection and interpretation of data (column 16 lines 61-67 and column 17 lines 1-43). Anderson et al. teach that there are different chambers for carrying out different functions, such as a sample collection chamber, an extraction chamber, an amplification chamber and a hybridization chamber (see above and column 23; further details are given, for example, in column 38 and throughout the reference). Anderson et al. teach that the system of the invention can be used in methods for diagnosing the presence of infectious agents and that the analyses can be performed in parallel on a large number of individual samples (column 39). Anderson et al. does not specifically teach food product testing.

Bruckner-Lea et al. teach strategies for automated sample preparation, nucleic acid purification of nucleic acids in environmental and food processing samples. Bruckner-Lea et al. teach that their automated fluidic system provides nucleic acids in a form suitable for PCR or microarray-based detectors. (See page 63). The mesofluidic system is described on page 64, and

state that the automated system is rapid and does not require a highly skilled technician (page 68). Bruckner-Lea et al. do not teach simultaneous detection of a plurality of species.

Bergeron et al. teach methods that use probes to rapidly detect and identify common bacterial pathogens. Specific probes for different bacterial pathogens are taught. Bergeron et al. teach that a pool of specific oligonucleotide probes is used to identify simultaneously more than one bacterial species (column 11, lines 64-67; column 13 lines 35-50). Bergeron et al. also teach that the method can be performed directly on samples obtained from food (see column 15, line 60, and claim 2). Bergeron et al. do not specifically teach probe arrays as a method of detection, and Bergeron et al. do not teach automated fluidics.

Nakayama et al. teach oligonucleotide primers complementary to sequences that encode genes related to pathogenicity, such as toxin genes, of pathogenic bacteria. Nakayama et al. teach that these are used as probes for detection of pathogens in samples, e.g., clinical isolates and food specimens (see column 1 and columns 3-4). The primers are used to amplify DNA from the suspected bacterial species. Nakayama et al. teach detection by agarose gel electrophoresis in the specification (see the figures and column12), although the method of detection in the claims is left open. Nakayama et al. do not teach probe arrays, automated fluidics, or database mining.

Tauxe reviews foodborne diseases, including information about when contamination occurs in the production process (see page 428; such information relates to the "process history parameters" of instant claim 9). Tauxe also reviews surveillance strategies, which include electronic systems (see page 430). The data from the surveillance is used to monitor outbreaks and to trace large-scale trends in foodborne disease (page 430) and the data is also used to

monitor foodborne parasitic and viral infections. Tauxe does not teach probe arrays or automated fluidics.

At the time of the invention of the instant application, one of ordinary skill in the art would have been motivated to detect a plurality of species in food products, since many microorganisms can contaminate food and cause disease. Since there are many different bacterial and other species that contaminate food, as reviewed by Tauxe, one would have been motivated to use a probe array that could detect more than one species simultaneously. Heyneker et al. teach probe arrays for detection of microorganisms in food samples and that a plurality of pools of probes can be put onto the array, and Bergeron et al. and Nakayama et al. teach specific probes for bacteria and teach that they can be used more than one bacterial species simultaneously. Bruckner-Lea teach the value of an automated fluidic system for preparing DNA for detection from samples, such as food samples (such as rapidity of the process), and Anderson et al. teach an automated fluidic system for preparing DNA and detection by probe arrays. Additionally, since Tauxe teach the value of electronic surveillance measures with respect to food, the ordinary artisan would have been motivated to put information into an electronic (hence, computer-operated) database and to mine the database for relevant information. Thus, it would have been obvious to one of ordinary skill in the art to combine the teachings of these references to detect species in food using automated preparation and amplification of DNA and probe arrays and to use databases. Success would have been expected.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Lisa J. Gansheroff whose telephone number is (703) 605-1203. The examiner can normally be reached 9 AM - 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Schwartz can be reached at (703) 308-1133. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Dianiece Jacobs whose telephone number is (703) 305-3388 or to the receptionist whose telephone number is (703) 308-0196.

LG
December 14, 2000

REMY YUCEL, PH.D
PRIMARY EXAMINER